Claim Rejections Under 35 U.S.C. § 102

The Examiner maintained her rejection of claims 1, 4-10, 13-19 and 22-27 under 35 U.S.C. § 102(e) as anticipated by Kim. On page 3 of the Office Action, the Examiner indicates that Applicants' argument that Kim does not anticipate the presently claimed invention because Kim does not teach an osmotic pressure less than 290 mOsm was not found to be persuasive. The Examiner states that Kim teaches NaCl as an iso-osmotic agent which is the same osmotic agent claimed by Applicants in claim 10. It is the Examiner's position that Kim teaches all of the components of Applicants' claimed composition and would inherently possess the same characteristics, i.e. an osmotic pressure of less than 290 mOsm. The Examiner states that the burden is on Applicants to prove that the claimed products are functionally different from those taught by the reference and to establish patentable differences.

Applicants respectfully traverse this rejection and submit a Declaration under 37 C.F.R. § 1.132 herewith which clearly establishes that the cited reference does not anticipate the claimed invention.

Applicants submit that the most important characteristic of the claimed invention is that the claimed composition has an osmotic pressure of less than 290 mOsm. As can be seen from the attached Declaration under 37 C.F.R. § 1.132, the preferred composition described in the Kim reference has an osmotic pressure of 319 mOsm, which is significantly higher than the upper limit of the claimed osmotic pressure, of "less than 290 mOsm". Therefore, the composition disclosed by Kim does not inherently possess all of the claimed characteristics of the claimed composition and the claimed composition is thus not anticipated by Kim.

Claim Rejections Under 35 U.S.C. § 103

On page 4 of the Office Action the Examiner maintains the rejections of claims 1-30 as unpatentable over Kim. The Examiner reiterates her position as set forth in the previous Office action, which is not repeated here for the sake of brevity.

Applicants respectfully traverse the rejection and submit that Kim does not teach or suggest an aqueous composition comprising a water insoluble or low water soluble substance, a medicament, and having an osmotic pressure less than 290 mOsm. In fact, Kim teaches away from the presently claimed invention by suggesting that the disclosed composition preferebly include an iso-osmotic agent which would not provide an osmotic pressure less than 290 mOsm as presently claimed and as established and explained in the Declaration under 37 C.F.R. § 1.132 filed herewith.

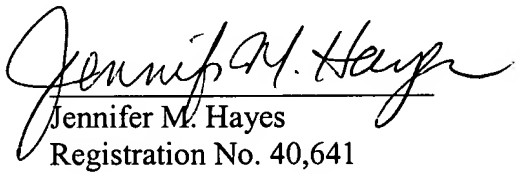
Kim teaches that the composition preferably includes an iso-osmotic agent which functions to prevent irritation to the nasal mucosa which indicates that the composition of Kim is almost the same osmotic pressure as that of the nasal mucosa. Further, it is an established rule that an osmolarity of a pharmaceutical composition for application to the nasal mucosa should be adjusted a little higher than that of the mucosal osmolarity (290 mOsm). Therefore, one of ordinary skill in the art would not be motivated to, or have a reasonable expectation of success in developing a composition for application to the nasal mucosa having an osmotic pressure of less than 290 mOsm as presently claimed.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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Date: August 13, 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

12/Declaration
1.132

In re Application of
Yoshihisa NISHIBE, et al.
Serial No.: 09/446,276
Filed: December 21, 1999
For: MEDICINAL COMPOSITIONS FOR APPLICATION TO MUCOSA

Group Art Unit : 1615
Examiner : Amy E Pulliam

DECLARATION UNDER 37 C.F. 1.132

Hon. Commissioner of Patents and Trademarks,
Washington, D.C. 20231

Sir:

I, Atsuhiro Nagano, c/o TEIJIN LIMITED, Pharmaceutical Products Research Laboratories, 4-3-2,Asahigaoka, Hino, Tokyo191-8512, Japan, do hereby declare:

That I am by profession a research scientist having earned a Master's degree in technology from Kyoto University in March 1998;

That I have been employed by TEIJIN LIMITED, Tokyo, Japan, since March 1998;

That I have been engaged in research into the development of pharmaceutical products in the same company to date;

That I am fully familiar with the above-identified U.S. application (hereinafter referred to as "present invention" for brevity);

That I have read and am fully familiar with the art cited against claims of the above-identified U.S. application (hereinafter referred to as "present application" for brevity);

That I personally conducted or supervised the conduct of all of the work reported in the examples including the comparative example in the specification of the present application, and the results obtained are as set forth therein;

That, to show that the present invention should be different from the cited prior art, I carried out the following explanations.

I would like to explain that the present invention differs from the cited prior art, USP 5,976,573 by Soo-Il Kim.

Kim teaches that *" the composition of the present invention includes preferably an iso-osmotic agent which functions to prevent irritation of nasal mucosa by the composition. ···omission··· Examples which can be used include sodium chloride, dextrose and calcium chloride (col. 6 lines 50-55)."*

It means that Kim's composition is almost the same osmotic pressure as that of nasal mucosa.

In addition, it is an established rule that an osmolarity of a pharmaceutical composition for application to the mucosa should be adjusted a little higher than the mucosal osmolarity (290 mOsm).

That is to say, the osmotic pressure of Kim's composition is never less than 290mOsm. Therefore the present invention differs from Kim's invention in their osmotic pressur of the composition.

In order to prove the evidence of the above mention, I prepared the preferred pharmaceutical composition described in the table of Kim's Example 1 and the osmolarity was measured.

Preparation, Osmolarity measurement and Conclusion are shown below.

1. Preparation

A composition comprising the components described in the following Table 1 was prepared. Preparation method was basically followed Kim's description.

Table 1

COMPONENT	Wt.%
mixture of microcrystalline cellulose and carboxyethylcellulose sodium	2.0
Polysorbate 80	0.004
disodium ethylenediamine tetraacetate	0.05
benzalkonium chloride solution	0.03
dextrose (anhydrous)	5.0
purified water	92.92

2. Osmolarity measurement

The osmolarity of the prepared composition was measured using the Micro-Osmometer Model 3MO from Advance Instruments, Inc.

3. Conclusion

The osmolarity of the prepared composition was 319 mOsm.

The prepared composition was different from Kim's composition *in the point that it did not contain triamcinolone acetonide, diluted hydrochloric acid and 0.1N NaOH solution.*

According to "van't Hoff law of osmotic pressure ", the osmotic pressure is proportional to the solute concentration. Triamcinolone acetonide is water-insoluble, so it does not affect the osmotic pressure.

Diluted hydrochloric acid and 0.1N NaOH solution are pH controlling agent and comprised amounts are extremely small. Therefore the influence of them on the osmotic pressure is very small.

Considering the above-mentioned points, the exact osmolarity of Kim's composition must be a little higher than 319 mOsm.

This examination comes to conclusion as follows;

It is an established common sense that the osmolarity of a pharmaceutical composition for application to the mucosa should be adjusted a little higher than the mucosal osmolarity (290 mOsm).

Kim's followed this rule and his invention is not an exception.

Hence Kim does not mention nor suggest the composition of the present invention its osmolarity must be lower than 290 mOsm.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 31 day of July 2001

永野 篤弘

Atsuhiro Nagano